

PRIONICS AG

Device and method for the visual analysis of test strips

Patent Claims

1. Device for the visual analysis of test strips (12), each comprising at least one delimited area (13) in which – after contact with a sample to be examined – a visually detectable signal can be generated, with
 - a) a positioning device (21) comprising at least one seat for:
 - aa) a test strip and/or
 - ab) a test strip unit (11) consisting of a plurality of test strips (12) connected in a defined spatial arrangement;
 - b) and an image generating device which graphically records at least one of the delimited areas (13) of a test strip arranged in a seat of the positioning device or of a test strip unit, and which transmits the recording result to an image analysis device,
 - c) with the image analysis device qualitatively and/or quantitatively analyzing the visually detectable signals for every test strip.
2. Device according to claim 1, **characterized in that** the positioning device (21) is designed to be handled separately from the image generating device and to be arranged on the image generating device.
3. Device according to claim 2, **characterized in that** the positioning device (21) and the image generating device are designed such that the positioning device can be reproducibly arranged in a defined arrangement on the image generating device.

4. Device according to any one of the preceding claims, **characterized in that** the image generating device is a scanner.
5. Device according to any one of the preceding claims, **characterized in that** the image analysis device consists of a computer with image processing software.
6. Device according to any one of the preceding claims, **characterized in that** the positioning device (21) consists of a frame, and the seats (22) for the test strip units (11) or the test strips consist of cutouts in the frame (21).
7. Device according to any one of the preceding claims, **characterized in that** the seats (22) are designed for the latching acceptance of the test strip units (11) or test strips.
8. Device according to any one of the preceding claims, **characterized in that** the positioning device (21) comprises at least two visually detectable position markers (23).
9. Device according to claim 8, **characterized in that** the image generating device graphically records the position markers (23) and transmits the recording result to the image analysis device which can localize and thus reproducibly detect the test strip units (11), the test strips (12) and/or the delimited areas (13) by means of the position markers (23).
10. Device according to any one of the preceding claims, **characterized in that** the test strip units (11) and/or the test strips comprise visually detectable, individualizing markings (14, 15).

11. Device according to claim 10, **characterized in that** the individualizing markings (14, 15) are bar codes.
12. Device according to claim 10 or 11, **characterized in that** the image generating device graphically records the individualizing markings (14, 15) and transmits the recording result to the image analysis device which identifies the individual test strip units (11) and/or the test strips (12) on the basis of the individualizing markings (14, 15), and which uses the data codified in the markings for the analysis, if necessary.
13. Device according to any one of the preceding claims, **characterized in that** the test strip units (11) and/or the test strips comprise at least two visually detectable position markers (16).
14. Device according to claim 13, **characterized in that** the image generating device graphically records the position markers (16) on the test strip units (11) and/or the test strips and transmits the recording result to the image analysis device which can localize and thus reproducibly detect the test strip units (11), the test strips (12) and/or the delimited areas (13) by means of the position markers (16).
15. Device according to any one of the preceding claims, **characterized in that** the positioning device (21) comprises a visually detectable gray scale (24) and/or a color scale (25).
16. Device according to claim 15, **characterized in that** the image generating device graphically records the gray scale (24) and/or the color scale (25) and transmits the recording result to the image analysis device which uses it for calibration of the analysis of the visually detectable signals on each test strip (12).

17. Device according to any one of the preceding claims, **characterized in that** the test strip unit (11) is designed such that the individual test strips (12) are arranged parallel to each other and spaced apart from each other such that their lower sections can be simultaneously inserted into neighboring sample tubes of a tube row of an integrated sample tube system.
18. Device according to claim 17, **characterized in that** the test strip unit (11) is designed such that a plurality of test strip units can be simultaneously inserted with their lower sections into different tube rows of an integrated sample tube system.
19. Device according to any one of the preceding claims, **characterized in that** the image analysis device performs a plausibility check by means of which will be checked whether

a test strip unit (11) or a test strip is arranged in all seats (22) of the positioning device (21); and/or
whether the individual test strip units (11) or test strips are arranged in a desired sequence in the seats of the positioning device (21); and/or
whether the test strip units (11) or test strips are from the same manufacturing batch; and/or
whether the best before date of the test strip units (11) or of the test strips is already reached.
20. Device according to any one of the preceding claims, **characterized in that** the image analysis device determines – on the basis of the recording result transmitted by the image generating device – the positions of the test strip units, the test strips and/or the delimited areas; identifies the individual test strip units, test strips and/or the delimited areas; and qualitatively and/or quantitatively analyzes the visually detectable signals for each test strip.

21. Device according to any one of the preceding claims, **characterized in that** the image analysis device localizes and thus reproducibly detects the test strip units (12), the test strips and/or the delimited areas (13) by means of position markers (16, 23) arranged on the positioning device (21), the test strip units (11) and/or the test strips, and graphically recorded by the image generating device.
22. Device according to claim 20 or 21, **characterized in that** the image analysis device identifies the individual test strip units (11), and/or the individual test strips by means of individualizing markings (14, 15) graphically recorded by the image generating device and arranged on the test strip units (11) and/or the test strips, and which uses the data codified in the markings (14, 15) for the analysis, if necessary.
23. Device according to any one of the preceding claims, **characterized in that** the image analysis device performs a plausibility check by means of which will be checked whether

a test strip unit (11) or a test strip is arranged in all seats (22) of the positioning device (21); and/or

whether the individual test strip units (11) or test strips are arranged in a desired sequence in the seats (22) of the positioning device (21); and/or

whether the test strip units (11) or the test strips are from the same manufacturing batch; and/or

whether the best before date of the test strip units (11) or of the test strips is already reached.
24. Positioning device for a device according to any one of the preceding claims, **characterized in that** it forms a surface graphically recordable by an image generating device and that it comprises seats for at least one test strip unit or at least one test strip.

25. Positioning device according to claim 24, **characterized in that** the positioning device consists of a frame (21), and the seats for the test strip units (11) or the test strips consist of cutouts in the frame (21).
26. Positioning device according to claim 24 or 25, **characterized in that** the seats (22) are designed for the latching acceptance of the test strip units (11) or test strips.
27. Positioning device according to any one of claims 24 to 26, **characterized in that** the positioning device (21) comprises at least two visually detectable position markers (23).
28. Positioning device according to any one of claims 24 to 27, **characterized in that** the positioning device (21) comprises a gray scale (24) and/or a color scale (25).
29. Method for the visual analysis of test strips comprising at least one delimited area (13) in which – after contact with a sample to be examined – a visually detectable signal can be generated, with at least one test strip or at least one test strip unit (11) – consisting of a plurality of test strips (12) combined in a defined spatial arrangement – being arranged in a seat (22) of a positioning device (21) – which can be arranged on an image generating device – such that the image generating device will be able to graphically record at least one of the delimited areas (13) of a test strip arranged in a seat of the positioning device or of a test strip unit, and that the recording result will be transmitted to an image analysis device which determines the positions of the individual test strip units (11), test strips (12) and/or the delimited areas (13) and identifies them, and qualitatively and/or quantitatively analyzes the visually detectable signal for each test strip (12).

30. Method according to claim 29, **characterized in that** position markers (16, 23) – arranged on the positioning device (21), the test strip units (11) and/or the test strips – are graphically recorded by means of the image generating device, and that the recording result will be transmitted to the image analysis device which can localize and thus reproducibly detect the test strip units (11), the test strips, and/or the delimited areas (13) by means of the position markers (16, 23).
31. Method according to claim 29 or 30, **characterized in that** the image generating device graphically records individualizing markings (14, 15) arranged on the test strip units (11) and/or the test strips, and transmits the recording result to the image analysis device which identifies the individual test strip units (11) or the test strips (12) on the basis of the individualizing markings (14, 15), and which uses the data codified in the markings for the analysis, if necessary.
32. Method according to any one of the claims 30 to 32, **characterized in that** the image generating device graphically records a gray scale (24) and/or a color scale (25) arranged on the positioning device (21) and transmits the recording result to the image analysis device which uses it as a calibration scale for the analysis of the visually detectable signals on each test strip (12).
33. Test strip unit (31) for use with a device according to any one of the claims 1 to 23, with a positioning device according to any one of the claims 24 to 28, as well as in a method according to the claims 29 to 32, consisting of a plurality of test strips (32) arranged in a defined spatial arrangement to each other and combined to a test strip unit (31), **characterized in that** the test strips (32) comprise an absorbable cut (35) in which at least one delimited area (33) each is provided, in which – after contact with a sample to be examined – a visually detectable signal can be generated.

34. Test strip unit according to claim 33, **characterized in that** the absorbable cuts (35) of the individual test strips (32) are designed as one piece connected with each other.
35. Test strip unit according to claim 33 or 34, **characterized in that** the test strip unit (51) comprises an edge reinforcement (54) arranged in absorbing direction above the delimited areas (53) and extending transversely to the test strips (52).
36. Test strip unit according to claim 33 or 35, **characterized in that** the test strip unit (61) comprises individual, non-contiguous test strips (62) which are connected with each other by means of a connecting device (64) arranged in absorbing direction above the delimited areas (63) and extending transversely to the test strips.
37. Test strip unit according to any one of the claims 33 to 36, **characterized in that** the absorbable cut (35) of the test strips is applied onto a stiff carrier material (34).
38. Test strip unit according to any one of the claims 33 to 37, **characterized in that** the test strip unit (31) is designed such that the individual test strips (32) are arranged parallel to each other and spaced apart from each other such that their lower sections are simultaneously insertable into neighboring sample tubes of a tube row of an integrated sample tube system.
39. Test strip unit according to any one of the claims 33 to 38, **characterized in that** the test strip unit (31) is designed such that a plurality of test strip units is simultaneously insertable into different tube rows of an integrated sample tube system.

40. Test strip unit according to any one of the claims 33 to 39, **characterized in that** the test strip unit (31) comprises a waste pad (36) arranged in absorbing direction above the delimited areas (33) which is used for the absorption of possibly excess liquid.

41. Stamping method for the production of a test strip unit in which a blank for a test strip unit (31) which consists of at least the material for the absorbable cut is placed onto a stamping plate (41) and at least the absorbable cut of the test strip unit is stamped out with a stamping tool (42), **characterized in that** the stamping plate (41) comprises a negative profile corresponding to the cut of the test strip unit (31) and that the blades of the stamping tool (42) used comprise a falling profile (43) which – during the stamping process – successively engages into the cutouts (44) of the negative profile of the stamping plate (41).